

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 70506-118
Send to SIG: check box
This material is:
New CSF Notification Final Printed Label Other: Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Roon 230).
Reviewer's Name: B. A. Akinlosoty
Phone: 703.605.0653 Division: RD
Date: 4/25/06



(under FIFRA, as amended)

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

NOTICE OF PESTICIDE:

x Registration

EPA Reg. Number. 70506-118

Date of Issuance:

04/18/06

Term of Issuance:

Conditional

Name of Pesticide Product:

Lambda-Cyhalothrin Technical

__ Reregistration

Name and Address of Registrant (include ZIP Code):

United Phosphorous, Inc. 423 Riverview Plaza Trenton, NJ 08611

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenicide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in enumerion with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. Make the following labeling changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No. 70506-118"

Signature of Approving Official:

Date

April 18, 2006

Zeorge LaRocca

Product Manager (RM 13)

Insecticide Branch

Registration Division (7505C)

EPA Form 8570-6

- b. Precautionary Statements/Hazard to Humans and Domestic Animals:
 - Revise the statements "Wear protective . . ." to read "Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Wear mask or respirator jointly aproved by MSHA/NIOSH with any N, R, P or HE filter".
 - Revise "Do not breathe vapors" to read "Do not breathe dusts".
 - Add "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals".
- c. Environmental Hazards: Revise "This pesticide is extremely . . ." to read "This pesticide is extremely toxic to fish and other aquatic organisms".
- d. Direction for Use: Add "Formulators using this product are responsible for obtaining EPA registration for their formulated product".
- e. Storage and Disposal / Container Disposal: You may include "Metal" in the subheading to read: "Metal or Plastic Containers".
- 3. Submit product chemistry data pertaining to product's octanol/water partition coefficient, water solubility, solubility in organic solvents, and vapor pressure.
- 4. Submit two (2) copies of the final printed label bearing the above stated revisions prior to releasing this product for sale.

If you fail to comply with the above stated conditions, this registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records. If you have any questions concerning this action, please contact Dr. B. A. Akinlosotu at (703) 605-0653.

Enclosure

LAMBDA-CYHALOTHRIN TECHNICAL

For Manufacturing Use Only in Formulating Insecticides.

ACTIVE INGREDIENT

Lambda-cyhalothrin	95.30%
INERT INGREDIENTS	
TOTAL.	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la expliquie a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes Call a poison control center or doctor for treatment advice.
 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, contact the National Pesticide Information Center 1-800-8587378.

FOR CHEMICAL EMERGENCY: spill, leak, fire, exposure, or accident call CHEMTREC I-800-424-9300

Manufactured for: United Phosphorus, inc. 423 Riverview Plaza Trenton, NJ 08611 1-800-247-1557 • www.upi-usa.com

EPA Reg. No. 70506-EPA Est. No. Net Contents:

ACCEPTED
with COMMENTS
In EPA Letter Dated:

APR 1 8 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING: May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Causes moderate eye injury. Avoid contact with eyes, skin, or clothing. Wear protective clothing, goggles or full face shield and rubber gloves. Do not breathe vapors. Wear mask or respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into an insecticide, for the following uses:

(1) Terrestrial and Aquatic Food: Alfalfa; Brassica (head and stem); Canola; Corn (field, pop, seed and sweet); Cotton; Fruiting Vegetable Group (except Cucurbits); Garlic; Legume Vegetable Group; Lettuce (head and leaf); Onion (dry bulb); Peanuts; Pome Fruits Group; rice; Sorghum; Stone Fruit Group; Sugarcane; Sunflower; Tree Nut Group; Triticale and Wheat.

Terrestrial Nonfood: non-crop lands (excluding public land); Tobacco (burley and flue-cured).

Forestry: Conifer and Deciduous trees (plantations, nurseries and seed orchards)

Domestic Indoor and Outdoor Non-Domestic Indoor and Outdoor

Nonfood Greenhouses and Nurseries

(2) Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

This product may be used to formulate products for specific use(s) not listed on the label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

PESTICIDE STORAGE: Keep container closed when not in use. Store in cool, dry place. Store in original container and out of reach of children, preferably in a locked storage area. In case of spill or leak on floor or paved surfaces, soak up with sand, earth, or synthetic absorbent. Rentove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Plastic Containers: Triple rinse (or equivalent); then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY

WARRANTY LIMITATIONS AND DISCLAIMER

United Phosphorus, Inc. (UPI) warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UPI EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Draft 9-30-05

DATE OUT: 24/MAR/2006



FEE: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]
DP BARCODE: D323519 RECEIVED DATE: 09/NOV/2005 FILE SYMBOL#: 70506-RRI
RODUCT NAME: Lambda-Cyhalothrin Technical MRIDs 463224-01 & -02
COMPANY NAME: United Phosphorus, Inc. FOOD USE [X] ACTION CODE: R31
PPC NUMBER OF THIS TGAI: 128897 DECISION NO.: 361151

FROM:

Sami Malak, Chemist De Malab

Technical Review Branch/RD (7505C)

Spm 03/24/06

TO:

13 George LaRocca/Bonaventure Akinlosotu

Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 03/OCT/2005, the applicant requested a "me-too" registration of subject product claiming its similarity to lambda-cyhalothrin technical, Reg. No. 100-1013. In support of this application, the applicant included product chemistry data, a proposed basic CSF dated 30/SEP/2005, label EPA received on 04/OCT/2005, and Certificate With Respect to Citation of Data.

FINDINGS:

- The subject product is a new TGAI produced by the applicant in Gujarat, India. The product, Lambda Cyhalothrin: [1 \pi(S), 3 \pi(Z)]-(\pm)-cyano(3-phenoxyphenyl) methyl-3-(2-chloro-3,3,3-trifluoro-I-propenyl)-2,2-dimethylcyclopropane carboxylate, CAS #91465-08-6, 95.3% pure.
- The subject product, an insecticide, will be used to formulate end-use products intended for insect control in crops.
 - 3. The subject product, is not similar in composition to lambda-cyhalothrin technical, Reg. No. 100-1013. The nominal concentration of subject product, 95.3%, does not fall within the certified limits of the registered product (89% ± 3%) calculated at 91.67% & 86.33%, respectively). Therefore, this review was conducted in accordance with FIFRA sec. 3(c)(5) or sec. 3(c)(7).
- The applicant should be advised to submit product chemistry data pertaining to product's octanol/water partition coefficient, water solubility, solubility in organic solvents, and vapor pressure. Non applicable studies must be supported with scientific and/or regulatory reasons.
- ✓ 4b. The submitted product chemistry data, although previously submitted but not reviewed because the product was withdrawn as per the applicant's letter dated 29/SEP/2005, is adequate and support registration of subject product.

- 5. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with Reg. No. 100-1013. An enforcement analytical method was described in this submission, MRID #463224-01. The method is reviewed in this memorandum.
- 6. The label claim nominal concentrations of 95.3% lambda-cyhalothrin is consistent with that in the basic CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.
- 7. The proposed basic CSF dated 30/SEP/2005, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food uses.

CONCLUSIONS:

After resolving Finding 4(a) above, the TRB will have no objections for registration of subject product. The proposed label EPA received on 04/OCT/2005 and basic CSF dated 30/SEP/2005 are acceptable as per Findings 6 & 7 above.

<u>REVIEW OF PRODUCT CHEMISTRY DATA:</u>

- 1. A statement of data confidentiality dated 11/FEB/2004was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data was moved to Confidential appendix A.
- 2. A GLP Statement dated 11/FEB/2004 was included with this submission to the effect that some of the submitted data was conducted in compliance with the GLP requirements of 40CFR§160.

Chemical Name (CAS, IUPAC, ANSI, etc.)	Lambda Cyhalothrin: [1×(S),3×(Z)]-(±)-cyano(3-phenoxyphenyl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate.
Chemical Numbers (CAS; PC Code)	Reg. No. 70506-RRI CAS No. 91465-08-6 PC Code 323519
Registration/Symbol No.	70506-RR1
Type of Product (T, FI, MP, EP)	95.3% T
DP Barcode	D323519
Reviewer	Sami Malak, Ph.D.

The applicant has submitted the following MRID of product chemistry data:

	Manufacturing and Im trifluoromethyl)pluenyl]-			umetralin Technical: 2-chloro-N-[2,6-enemethanamine
GR <u>N</u>	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients	463224-01	A	For product identity refer to text below. For product's composition refer to Confidential Appendix A for details.
830.1600 830.1620	Starting Materials & Manufacturing Process	463224-01	A	Refer to Confidential Appendix A for details.
830.1670	Discussion of	463224-01	A	Refer to Confidential Appendix A for

details.

details.

details.

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Refer to Confidential Appendix A for

Refer to Confidential Appendix A for

Refer to text for details

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.

² Refer to CBI Appendix A for details.

Impurities

Preliminary Analysis

Certification of Limits

Analytical Methods

830.1700

830.1750

830.1800

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

463224-02

463224-01

463224-01

830-1550 Product Identity and Composition

The subject product is a new TGAI produced by the applicant in Gujarat,India. The product, Lambda cyhalothrin technical: [1~(S),3~(Z)]-(±)-cyano(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate is 95.3% pure.

Chemical name: $[1 \times (S), 3 \times (Z)]$ -(\pm)-cyano(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate

Common Name: Lambda cyhalothrin

Trade Name: Lambda cyhalothrin technical insecticide.

CAS #: 91465-08-6

Product category: Insecticide

Molecular Formula: C₂₃H₁₉Cl F₃ NO₃

Molecular Weight: 449.9

Molecular Structure:

830-1600 <u>Description of Materials Used to Produce the Product</u>: Refer to Confidential appendix A.

830-1620 <u>Description of Production Process</u>: Refer to Confidential appendix A.

830-1620 <u>Discussion of Formation of Impurities</u>: Refer to Confidential appendix A.

830-1700 <u>Preliminary Analysis</u>: Refer to Confidential appendix A.

830-1750 <u>Certified Limits</u>:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with Reg. No. 100-1013. An enforcement analytical method was described in this submission, MRID #463224-01.

The method described is gas chromatograph with a flame ionization detector (GC/FID). The method was employed to determine Cyhalothrin in the technical material. In this method the sample is dissolved in dichloromethane containing hexacosane as an internal standard. Separation is carried out in the split injection mode using dimethyl polysiloxcane WCOT fused silica capillary column with automatic injection and flame

ionization detector. The lambda cyhalothrin is determined by comparison with calibration solution.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample chromatograms and calculations are included with this submission.

Physical and Chemical Properties, Subgroup B, Series 830.6302 to -830.7300 (40 CFR 158.190)

Guidefine Reference NO.(GRN 830.)/Title	Data Fulfilled	Value or Qualitative Description	MRID No.
.6302 Color	Y	White.	463224-02
.6303 Physical state	Y	Powder.	463224-02
.6304 Odor	Y	Odorless.	463224-02
.6313 Stability	Y	The accelerated stability at 40°C revealed product's stability for a period of tow weeks. Stable to elevated temperature of. No test was conducted with metals and metal ions because it will not come in contact with metals or metal ions.	463224-02
.6314 Oxidation- Reduction/Chemical Incompatibility	Y	The product does not contain any oxidizing or reducing agents,	463224-02
.6315 Flammability	NA	Solid.	463224-02
.6316 Explodability	Y	Not considered to be explosive.	463224-02
.6317 Storage Stability	Y	Initial results indicated product's stability when stored under warehouse conditions.	463224-02
.6319 Miscibility	NA	Not required for a TGAI. It is not intended to be mixed with petroleum distillates.	4(3224-02
.6320 Corrosion Characteristics	Y	No corrosivity to the packaging containers during the period of the storage stability study,	463224-02
.6321 Dielectric breakdown voltage	NA	Is not to be used around electrical equipment.	463224-02
,7000 рН	Y	7.58.	463224-02

.7050 UV/Visible absorption	Y	The UV-Visible absorption spectra was 1.464 @214 nm for neutral solutions (pH 7.02), 1,423 @213 nm for acidic solutions (pH 0.86), and 1.221 @ 225 nm for basic solutions (pH 12.55).	463224-02
.7100 Viscosity	NA	Product is a TGA1 & solid.	463224-02
.7200 Melting Point	Υ·	49.3°C	463224-02
.7300 Density/relative density/bulk density	Y	1.3 g/ml @ 20°C	463224-02
.7370 Dissociation Constant	NA	The product does not dissociate in acidic or basic medium and does not have any dissociation constant.	463224-02
.7550 Partition coefficient	Not submitted		
.7840 Water solubility	Not submitted		
.xxxx Solubility in Organic Solvents	Nat submitted	·	
.7950 Vapor pressure	Not submitted		

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires apparating; I = Incomplete or in progress; W = Waived.

Attachment:

Confidential Appendix A (pages 7-13).

Page	is not included in this copy.
Pages	19 through 17 are not included in this copy.
	aterial not included contains the following type of mation:
<u> </u>	Identity of product inert ingredients.
	Identity of product impurities.
	Description of the product manufacturing process.
· · · · · · · · · · · · · · · · · · ·	Description of quality control procedures.
·	Identity of the source of product ingredients.
· · ·	Sales or other commercial/financial information.
· · · · · · · · · · · · · · · · · · ·	A draft product label.
· .	The product confidential statement of formula.
	Information about a pending registration action.
· .	FIFRA registration data.
	The document is a duplicate of page(s)
· · · · · · · · · · · · · · · · · · ·	The document is not responsive to the request.
·	Internal deliberative information.
· ·	Attorney-Client work product.
	Claimed Confidential by submitter upon submission to the Agency.

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830-1670 Discussion of Formation of Impurities:

Potential impurities present in the reactions are generally carry over materials used in the production, unreacted intermediates, minor contaminants found in the raw materials that may include:

830-1700 Preliminary Analysis:

Five batch analysis were performed in duplicate on lambda-cyhalothrin Technical. The applicant reported the same ingredients, nominal concentrations, and upper/lower limits as those reported in the basic CSF dated 30/SEP/2005.

830-1750 Certified Limits:

The applicant reported the same certified limits as those found in duplicate analysis of five batches of lambda-cyhalothrin technical as reported in the proposed basic CSF dated 30/SEP/2005.



United Phosphorus, Inc.

423 Riverview Plaza Trenton, NJ 08611 (609) 392-8200 (phone) (609) 392-0808 (fax) Ann M. Tillman Technical Director

October 3, 2005

Document Processing Desk (APPL)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 Bell Street
Arlington, VA 22202

Attn: G. Larocca, PM 13

Re: United Phosphorus, Inc. - Lambda-Cyhalothrin Technical

(EPA File Symbol 70506-)

Me-Too Application for New Pesticide Registration

United Phosphorus, Inc. (UPI) is submitting an application for a registration of its Lambda-Cyhalothrin Technical. This product is substantially similar to the already registered product EPA Reg. No. 100-1013.

Enclosed with this letter, please find the following items:

- 1. Application for Pesticide Registration (EPA Form 8570-1).
- 2. Confidential Statement of Formula (EPA Form 8570-4) dated September 30, 2005.
- 3. Data matrix forms Agency Use and Public File copies (EPA Form 8570-35) dated October 3, 2005.
- 4. Certification with Respect to citation of Data (EPA form 8570-34)
- 5. Five (5) copies of the proposed container labeling.
- 6. A list of previously submitted studies in support of this application.

This action should fall within the PRIA category R31, "New product, Non Fast track" with a PRIA fee of \$4,200. 1 can be contacted by email at atillman@upi-usa.com.

Please note that we are relying upon the cite-all method to satisfy data requirements other than product specific product chemistry data. Data were submitted with a previous submission (submitted July 16, 2004, Decision Number D-346526, File Symbol 70506-TN) for registration for UPI's Lambda-Cyhalothrin Technical but a request was submitted to withdraw that submission without prejudice. *The previously submitted data are being*

used to support this application for registration. No new data are required to support this registration action.

Please let me know if you have any questions about this application or if any additional information is needed.

Sincerely,

Ann M. Tillman Technical Director

United Phosphorus, Inc.

Enclosures

REGISTRATION NO. 70.0%

CONFIDENTIAL STATEMENT OF FORMULA ENGLOSED

SUBMITTE

APPLICANT

SUBMITTED

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or to reveal, other than to the Secretary or officials or employees of the Secretary may prescribe, any information relative to formulas of or to the courts in response to a subpoena, or to physicians, and in emergencies to pharamacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as It shall be unlawful for am person to use for his own advantage the United States Department of Agreatme or other Federal agencies. products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act



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